

In re Patent Application of
John Alfred Wilkinson
Serial No. 10/019,353
Filed April 25, 2002

REMARKS

Applicant herein responds to the outstanding Office action and requests that the Examiner take notice of new counsel, as per the undersigned.

The Claims Are Definite

The Examiner's concerns regarding the clarity of the language in claims 8 and 82 have been addressed. While the Office action stated that claim 81 was rejected on the basis of Section 112, Applicant believes this claim identification resulted from a typographical error and that the Examiner really meant to reject claim 82, as it is this claim that contains the language reciting certain content of water. Accordingly, claims 8 and 82 have been amended to indicate that it is the "gel carrier", rather than the gelling agent, that may contain from about 0.1 to about 95% v/v water. In view of these amendments, Applicant respectfully requests that the Examiner withdraw the claim rejections under Section 112.

The Cited Reference To Burke et al. Represents Non-Analogous Art

The scope of analogous art, according to Judge Randall Rader, turns on: (1) whether the art is from the same "field of endeavor," regardless of the problem addressed; and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is "reasonably pertinent" to the particular problem with which the inventor is involved. The identification of analogous prior art is a factual question reviewed by courts for substantial evidence, he added. In re Bigio, 381 F.3d 1320 (Fed. Cir., 2004), 72 USPQ2d 1209.

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This test requires the PTO to determine the appropriate field of endeavor from explanations of the invention's subject matter in the patent application, the court explained, including the embodiments, function, and structure of the claimed invention. The assessment of the field of endeavor is not a wholly subjective call, Judge Rader observed, since there must be a basis in the application for limiting or expanding the scope of the field of endeavor.

The patent publication by Burke et al. clearly states what its field of endeavor is, specifically in paragraph 0002, "[t]he present invention relates to an universal antiviral composition." It is apparent that the principal utility of the Burke et al. invention is as an antiviral composition. The composition may be applied to various body parts, including the epidermis. However, the biological activity of the Burke et al. composition is directed primarily against viruses, with the added benefit of also being a spermicide.

In contrast, the present invention is directed to an insecticidal composition particularly effective against sucking lice and head lice, that is, against multicellular organisms which are ectoparasites of skin on animals and humans. This is a totally different field of endeavor than that to which the Burke et al. invention is directed. Burke et al. deal with viruses, which are smaller than single cells and are obligate intracellular agents, whereas ectoparasites orders of magnitude larger than single cells (they are multicellular) and are obligate extracellular agents, or the exact opposite of viruses.

The determination that a reference is from a nonanalogous art is twofold. First, it is necessary to decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved.

The Burke et al. invention is directed to killing a virus, an obligate Intracellular agent that can only reproduce once it is inside a host cell. The Burke et al. invention also kills

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sperm cells and is used as an aid in contraception within the vaginal tract. These problems addressed by Burke et al. are far afield from the problem dealt with in the present invention, killing relatively large multicellular ectoparasites which, unlike viruses, are restricted to living on the outer layers of the host's skin. Those skilled in these arts will recognize that drugs and compositions which are effective against viruses are necessarily very different in form and function from those used on ectoparasites and will generally be ineffective against those. For those reasons, someone skilled in the art of treatment of ectoparasites would not be expected to look to the literature of antivirals for guidance or teachings applicable to ectoparasites.

Accordingly, because the Burke et al. invention is not in the same field as the present invention, and because Burke et al. address a problem totally different from that addressed by Applicant's invention, the cited reference by Burke et al. constitutes non-analogous art and is not properly relied on in an obviousness rejection.

Applicant has argued that the Burke *et al.* reference is non-analogous art because it is primarily directed to virucidal compositions and viruses are obligate intracellular agents. The Greff and Sine *et al.* references provide compositions to treat skin affected by bacteria, which typically are not intracellular agents as viruses are. The bacteria, therefore, remain generally on top of the skin, as do the lice and other ectoparasites against which the present composition is directed.

The Claims Are Nonobvious Over The Combined References

The pending claims have been rejected by the Examiner as obvious and unpatentable under Section 103(a) over Eini (EP Publication No. 0 495 684 A1), in view of Greff (6,123,953), or Burke et al. (2002/0151521), or Sine et al. (6,183,766). As

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discussed above, Applicant asserts that the reference by Burke et al. constitutes non-analogous art and is, therefore, not properly relied on in a rejection.

Accordingly, these comments will focus on the references by Eini, Greff and Sine et al. In addition, claims 1 and 75 are the only pending independent claims, consequently Applicant will direct these remarks to these two claims which, if found patentable, their respective dependent claims will also be patentable, as they add yet additional distinguishing features to the claimed invention.

Applicant respectfully asserts that the Examiner has not established a *prima facie* case of obviousness against claims 1 and 75. In establishing a *prima facie* case of obviousness, three elements must be established (MPEP §2143):

- 1) that the prior art contains a suggestion or motivation to combine the cited references in such a way as to achieve the claimed invention;
- 2) that one skilled in the art at the time the invention was made would have reasonably expected the claimed invention to work; and
- 3) that the combination must teach or suggest all the claim limitations, that is, that the combination produces the claimed invention.

Applicant respectfully points out that the Examiner has previously recognized that the Eini reference does not mention or suggest a gel based on polymethacrylate, and that Eini does not teach the use of *Aloe vera* in such a gel. Applicant conducted a search of an electronic copy of the Eini reference and found no mention of or teaching related to polypropylene glycol. Accordingly, those skilled in the art would find nothing in the Eini reference that would guide them to achieving the invention recited in independent claim 1, which includes a synthetic gelling agent containing glyceryl polymethacrylate and propylene glycol. The skilled would also find no teaching in the Eini reference that would lead them to arrive at the invention of independent claim 75, which recites a composition

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comprising at least one anti-pruritic agent containing an extract of *Aloe vera*. Absent those teachings in the Eini reference, the obviousness rejections must rely on the additional references cited by the Examiner in order to meet at least requirements 1 and 3 above.

Applicant searched the text of the Greff reference electronically and found no mention or suggestion of the use of essential oil(s), or of *Aloe vera*, or of an anti-pruritic agent. Accordingly, even if the teachings of Greff were combined with those of Eini, the combination would not produce the invention recited in claims 1 and 75. Therefore, this combination fails to meet element 3 of the *prima facie* case of obviousness, that is, the combination does not produce the claimed invention.

Additionally, the text of the Sine *et al.* reference was also searched electronically by Applicant, who found that this reference does not teach or suggest the use of *Aloe vera* or of an anti-pruritic. Thus, if the Eini reference were combinable with the teachings of Sine *et al.*, the present invention would not be produced. In fact, even if Eini, Greff and Sine *et al.* were combined, the combination would not produce the present invention, as teachings or suggestions of the incorporation of *Aloe vera* or of an anti-pruritic are missing from the combination.

Thus, at least element 3 of the *prima facie* case of obviousness has not been established, therefore, the presumption remains that the claimed invention is non-obvious. For that reason, Applicant is not required to make a showing of criticality, as suggested by the Examiner. It is only after a *prima facie* case of obviousness has been established that the burden of proof shifts to Applicant to rebut the *prima facie* obviousness by providing evidence of criticality.


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Conclusion

In view of the amendments and the remarks presented herein, it is submitted that claims 1 and 75 are patentable. In addition, their respective dependent claims, which recite yet further distinguishing features, are also patentable and require no further discussion.

If the further prosecution can be facilitated through a telephone conference between the Examiner and the undersigned, the Examiner is respectfully requested to telephone the undersigned.

Respectfully submitted,



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